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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/050,848 01/18/2002 Norman G. Anderson 2315-148 3044

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EXAMINER
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LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/25/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/050,848	ANDERSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Frank W Lu	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 August 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-55 is/are pending in the application.
  - 4a) Of the above claim(s) 7-10,12,14-17,26-29,31,33-36,45-48 and 52-55 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6,11,13,18-25,30,32,37-44,49, and 51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Disposition of Claims

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 1/18/2002 (original) is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1.5</u> .	6) <input type="checkbox"/> Other: _____ .

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**DETAILED ACTION**

*Election/Restriction*

1. Applicant's election with traverse of Group I, claims 1-17, species 5(1) (claims 6, 25, and 44), species 6 (1) (claims 13, 32, and 51), and species 7(1) (claims 1, 21, and 40) in Paper No. 4 is acknowledged. The traversal is on the ground(s) that: (1) "all of the claims should be examined together because, as the Office Action makes clear, all of the claims are classified together in class 422, subclass 102"; (2) "a search for one centrifuge tube of one diameter is an integral part of a search for the other"; and (3) "no election of species is necessary or appropriate." since "[T]he differences are merely numerical differences between centrifuge speeds and tube size. Searching one species involves inherently searching all other species and thus the consideration of these numerical values ought to be no undue burden.".

After carefully consider applicant's arguments, the examiner agreed to withdraw the restriction requirement. However, the arguments have not been found persuasive toward the withdrawal of the species election nor persuasive toward the relaxation of same such that all species will be examined together. "Searching one species involves inherently searching all other species" was not reason for specie election. The species election was based on that these species are patentably distinct. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Therefore, the species election is still deemed proper and is therefore made FINAL and claims 1-6, 11, 13, 18-25, 30, 32, 37-44, 49, and 51 will be examined.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6, 11, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as vague and indefinite in view of the phrase "wherein that inner diameter was small enough to trap an air bubble between two layers of aqueous liquid such that the air bubble would keep said two layers of aqueous liquid separate so long as said centrifuge tube" because it is unclear that "that inner diameter" is inferred to the centrifuge tube with option (I) or the centrifuge tube with option (ii) or both centrifuge tubes with options (I) or (ii). Please clarify.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

5. Claims 1-3, 6, 11, 13, 18, 20-22, 25, 30, 37, 39-41, 44, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton *et al.*, (US Patent No. 4,106,907, published on August 15, 1978) in light of Lee *et al.*, (US Patent No. 3,948,823, published on April 6, 1976)

Charlton *et al.*, teach centrifuge tube and method for performing radio-immunoassay. As shown in Figure 1, centrifuge tube 1 with cylindrical shape comprised an upper region, a middle region and a low region wherein an inner diameter of said upper region was larger than an inner diameter of said middle region, wherein an inner diameter of said middle region was larger than an inner diameter of said low region, and wherein said lower region has a closed bottom as recited in claims 1, 18, and 37. Said inner diameter of said low region was  $d=0.157$  inch ( $d=4.6$  mm) and was 13.6% to 15.8% of the total length of said tube ( $f/c=(7.5-15 \text{ mm})/(55-95 \text{ mm})$ ) as recited in claims 2, 3 , 21, 22, 40, and 41 (see column 3). Note that: (1) since the specification does not give definition for ultracentrifuge tube, any regular centrifuge tube could be considered as an ultracentrifuge tube as recited in claims 1, 18, and 37; (2) although Charlton *et al.*, did not directly show that inner diameter was small enough to trap an air bubble between two layers of aqueous liquid such that the air bubble would keep said two layers of aqueous liquid separate so long as said centrifuge tube is at rest as recited in claims 1, 20, and 39, this limitation was considered to be inherent to the patent taught by Charlton *et al.*, since Lee *et al.*, showed that a centrifuge tube itself could trap an air bubble after agitated solution was added into the centrifuge tube and this air bubble could be removed after centrifugation (see column 10). This air bubble

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could be considered to be located between two layers of aqueous liquid such that the air bubble would keep said two layers of aqueous liquid separate so long as said centrifuge tube is at rest since the air bubble separated the solution and could only be removed after centrifugation; and (3) as shown in Figure 2, said upper region of the centrifuge tube had an outer diameter larger than an outer diameter of said low region as recited in claims 13, 32, and 51.

Regarding claims 6, 25, and 44, although Charlton *et al.*, did not directly show that the centrifuge tube could be centrifuged at velocities high enough to band viruses in CsCl gradient without said tube breaking, this limitation was considered as an intended use of the centrifuge tube taught by Charlton *et al.*, since a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claims 11, 30, and 49, although Charlton *et al.*, did not directly show that the centrifuge tube was made of polycarbonate, Charlton *et al.*, taught that the centrifuge tube was made of any organic plastic material (see column 2, lines 37-39).

Therefore, Charlton *et al.*, in light of Lee *et al.*, teach all limitations recited in claims 1-3, 6, 11, 13, 18, 20-22, 25, 30, 37, 39-41, 44, 49, and 51.

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 4, 23, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton *et al.*, in light of Lee *et al.*, as applied to claims 1-3, 6, 11, 13, 18, 20-22, 25, 30, 37, 39-41, 44, 49, and 51 above, and further in view of Simmonds *et al.*, (US Patent No. 4,260,873, published on April 7, 1981).

The teachings of Charlton *et al.*, light of Lee *et al.*, have been summarized previously, *supra*.

Charlton *et al.*, light of Lee *et al.*, do not disclose to polish the inner surfaces of a centrifuge tube using vapor polishing as recited in claims 4, 23, and 42.

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Simmonds does teach to polish the inner surfaces of a centrifuge tube using vapor polishing (see columns 1 and 2). .

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used a vapor polishing agent to polish the inner surfaces of a centrifuge tube in view of the patent of Simmonds. One having ordinary skill in the art would have been motivated to polish the inner surfaces of a centrifuge tube described by Charlton *et al.*, because vapor polishing would remove oxidized plastic, dissolve uncovered plastic in a centrifuge tube, and make a smooth inner surface of the centrifuge tube (see Simmonds *et al.*, column 1). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to polish the inner surfaces of a centrifuge tube using vapor polishing.

8. Claims 5, 24, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton *et al.*, in light of Lee *et al.*, as applied to claims 1-3, 6, 11, 13, 18, 20-22, 25, 30, 37, 39-41, 44, 49, and 51 above, and further in view of Saunders *et al.*, (US Patent No. 5,550,060, published on August 27, 1996).

The teachings of Charlton *et al.*, light of Lee *et al.*, have been summarized previously, *supra*.

Charlton *et al.*, light of Lee *et al.*, do not disclose to a centrifuge tube whose inner surfaces are coated with an adhering polymer as recited in claims 5, 24, and 43.

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Saunders *et al.*, do teach to coat the inner surfaces of a centrifuge tube with an adhering polymer (see columns 11 and 12).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have coated the inner surfaces of a centrifuge tube with an adhering polymer in view of the patent of Saunders *et al.*. One having ordinary skill in the art would have been motivated to modify the centrifuge tube described by Charlton *et al.*, because a centrifuge tube having an inner surface coating could improve cell separation result (see Saunders *et al.*, second paragraph in column 6 and claim 1 in column 16). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to coat the inner surfaces of a centrifuge tube with an adhering polymer.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-6, 11, 13, 18-25, 30, 32, 37-44, 49, and 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No.6,254,834. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 1-6, 11, 13, 18-25, 30, 32, 37-44, 49, and 51 in this instant application are not identical to claims 1-25 of US Patent No. 6,254,834, claims 1-25 in US Patent No. 6,254,834 are directed to the same subject matter and fall entirely within the scope of claims 1-6, 11, 13, 18-25, 30, 32, 37-44, 49, and 51 in this instant application. In other words, claims 1-6, 11, 13, 18-25, 30, 32, 37-44, 49, and 51 in this instant application are anticipated by claims 1-25 of US Patent No. 6,254,834.

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***Conclusion***

9. No claim is allowed.
10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu  
October 16, 2002

  
ETHAN C. WHISENANT  
PRIMARY EXAMINER